



AmerisourceBergen Corporation  
Corporate Security & Regulatory Affairs  
P.O. Box 959  
Valley Forge, PA 19482  
1300 Morris Drive  
Chesterbrook, PA 19087-5594  
[www.amerisourcebergen.com](http://www.amerisourcebergen.com)

Steve Mays  
Director, Regulatory Affairs  
Phone 610.727.7467  
Fax 610.727.3650  
[smays@amerisourcebergen.com](mailto:smays@amerisourcebergen.com)

## Memorandum

**TO:** Distribution Center Managers, Compliance Coordinators  
**FROM:** CSRA  
**CC:** Regional Vice Presidents  
**DATE:** October 25, 2004  
**SUBJECT:** ABC Awarded DEA Certificate of Appreciation

As many of you already know, CSRA regularly provides training for Diversion Investigator Trainees from DEA's Quantico, VA training academy. This training takes place at AmerisourceBergen's (ABC) Richmond Distribution Center (DC) and includes a tour of the facility.

At the conclusion of the training on Friday, October 22, 2004, DEA presented ABC with a Certificate of Appreciation in recognition of ABC's contribution to drug enforcement and to DEA's training program. Steve Mays accepted the award on behalf of AmerisourceBergen.

This is a well-deserved recognition of ABC's regulatory compliance program and cooperative relationship that all DCs have with the DEA. This award would not be possible without the cooperation and participation of Richmond DC management and associates. CSRA would like to thank all associates for their continued commitment to compliance.

Congratulations on your Award!

AM-WV-00785

# **Pharmaceutical Wholesale Drug Industry Regulatory Compliance**

**Presented by AmerisourceBergen  
Corporation in cooperation with the Drug  
Enforcement Administration**

Steve Mays  
Director, Regulatory Affairs  
Corporate Security and Regulatory Affairs  
(CSRA) Dept.  
AmerisourceBergen Corporation (ABC)  
Valley Forge, PA

# Statement of Goals

- The goal of this program is to provide the participants with an overview of the Pharmaceutical (Drug) Wholesale industry and the Wholesaler's compliance with 21 C.F.R. 1300 to the End. In addition, we will provide examples and methods of standard operating procedures of a full-line pharmaceutical wholesaler in an attempt to educate and thus enhance and build on the good working relationship between the Industry and DEA.

# Objectives

At the end of the presentation attendees should:

- Understand the basic functions of a drug wholesaler with regard to distribution of controlled substances
- Be familiar with the basic structure and departments of a drug wholesaler
- Understand the Industry, basic operations and procedures and how they relate to 21 CFR 1300 to the end
- Evaluate and understand the different types of reports and documents available during an audit



# Wholesale Drug Distributors

- There are over 3,000 different manufacturers of pharmaceuticals and health care products in the United States
  - ABC maintains approximately 140,000 SKUs (stock keeping units)
- There are over 130,000 pharmacy sites in the U.S.
  - Retail
  - Closed Door
  - Hospital

# ROLE OF THE WHOLSALE DISTRIBUTOR

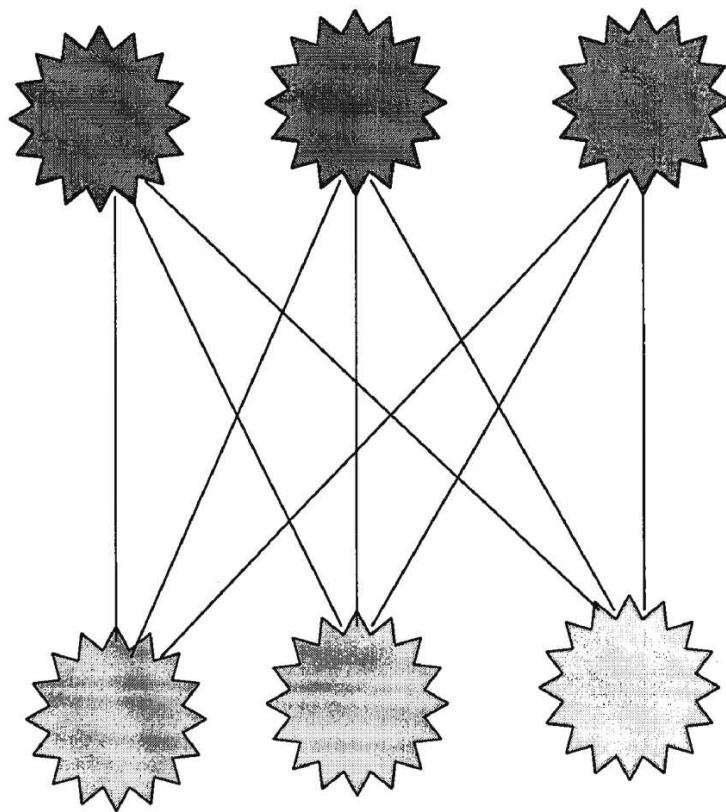
Manufacturers

Pharmacies

## Without Distributors

Confusion and Complexity

If all 130,000 pharmacy sites ordered product from all 3,000 manufacturers once a month the industry would generate 4.9 billion transactions each year

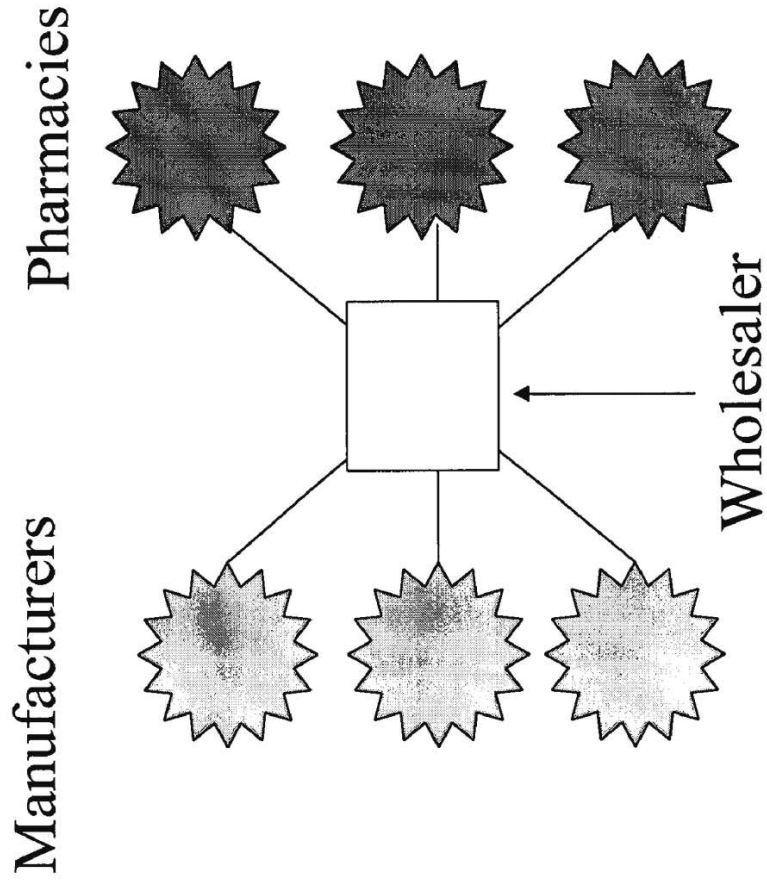


# ROLE OF THE WHOLESALER DISTRIBUTOR

## With Distributors

Control and Common  
Sense

Utilizing the 80 drug  
wholesalers that  
number is cut to 124  
million transactions  
(97% reduction in  
transactions)





# Wholesale Drug Distributors

- There are approximately 80 wholesalers who operate approximately 230 distribution centers nationwide which generate approximately \$120 billion in sales annually
- The top 3 wholesalers account for approximately 90% of the market
- In the past decade the industry has cut operating expenses by over 30 percent
- Cutting operating expenses has not curbed the steady decline in profit margins
- Average product mark-up is 1%
- Estimated net profits for Wholesale Drug Distributors is less than 1 percent (0.65%) of sales

## **Cost of Inadequate Compliance**

- Sales Dollars required to recover loss:
  - \$1,000 loss @ 1% profit margin would require approximately \$100, 000 in sales to recover the loss.
  - \$10,000 loss @ 1% profit margin would require approximately \$1,000, 000 in sales to recover the loss.
  - \$50,000 loss @ 1% profit margin would require approximately \$5,000, 000 in sales to recover the loss.

# AmerisourceBergen Corporation

- AmerisourceBergen is the largest pharmaceutical services company in the United States dedicated solely to the pharmaceutical supply chain. It is the leading distributor of pharmaceutical products and services and is also a leader in the long term care pharmacy and workers' compensation fulfillment marketplaces.
  - ABC has been in business since 1889
  - ABC 2004 annualized revenue - \$47 billion
  - Employs 14,000 people
  - ABC is ranked #22 on the Fortune 500 list
  - ABC is ranked #6 in the 2003 *Business Week* 50, a list of best performing companies in the S & P 500
  - Operates 170 separate DEA registered locations
- ABC subsidiaries (ABSG, Pharmerica, AHP)

# **AmerisourceBergen Drug Company**

- **Operational Time Line (six days/week)**
  - **Receiving (6:00am - 2:00pm)- approx. \$125-190 million daily**
  - **Ordering (6:00am - 9:00pm) - approx. 100 - 1,000 night Avg.**
  - **Picking (12:00pm - 3:00 am) - approx. 10K - 70K Lines Avg.**
  - **Shipping (10:00pm - 6:00am)**
  - **Delivery (7:00 am - 4:00pm)**



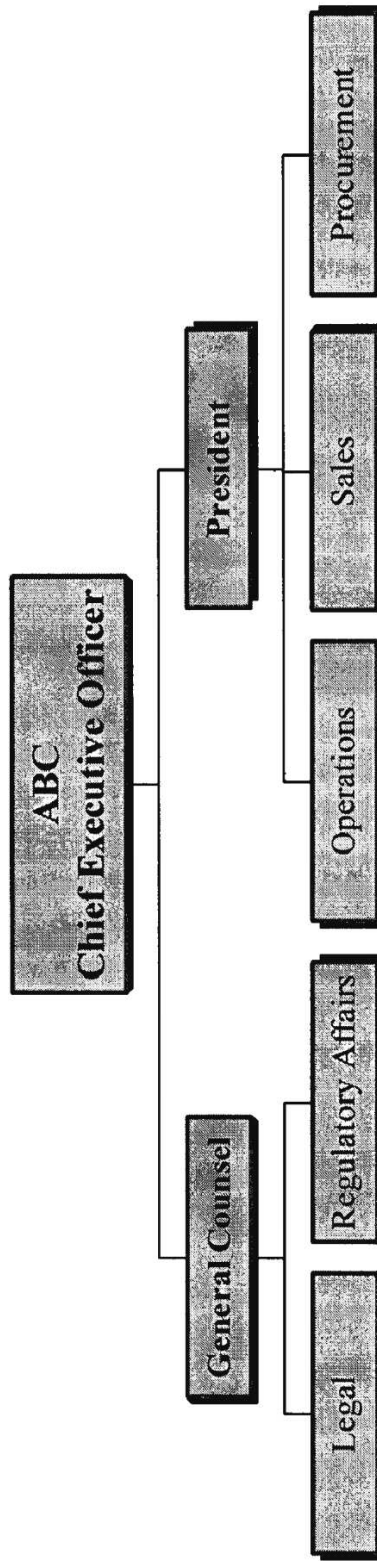
## **AmerisourceBergen Commitment to Compliance**

- Regulatory Compliance is driven operationally on a daily basis at each individual distribution site with oversight, guidance, and assurance from the corporate office.
- Six-Hour Security & Regulatory Compliance Training Program for “compliance critical” Associates.



# AmerisourceBergen Commitment to Compliance

- Separation of Duties (Operations & Compliance) ensures the integrity of the program



- “The Network” – A toll free anonymous reporting hotline.  
(1.800.NETWORK)

## **AmerisourceBergen Commitment to Compliance**

- Each of ABC's 38 Distribution Centers (DCs) have a Compliance Coordinator responsible for monitoring adherence to state and federal regulations and company policy & procedures.

### **Corporate Support Function:**

- - Regulatory Affairs Supervisor for each region
  - Audit each Distribution Center regularly
  - Annual Compliance Training Conference
  - Periodic Alerts & Updates
  - Quarterly Newsletter
  - Internal Website

# **AmerisourceBergen Drug Company**

- DEA Audits/Inspections
  - Average approximately 12 audits each year
  - Each distribution center audited once every 3-5 years
- ABC Security and Regulatory Compliance Audits
  - Average approximately 30 audits each year
  - Each distribution center audited once every 6 - 18 months
- Other Regulatory Agencies Impacting Distribution
  - FDA (PDMA & New Food Handler Registration)
  - State Boards of Pharmacy/Departments of Health
  - Dept. of Transportation/FAA
  - OSHA
  - EPA (Rx Waste)
  - HIPAA (Patient Privacy)
  - Bureau of Wholesale Furniture

# Code of Federal Regulations

- Interpretation
  - Between different facets of the Industry (Phcy, Dist, Mfg's)
  - Between Industry and DEA
  - Between DEA Field Offices and/or Washington



# 21 CFR 1301 - Security

- 1301.71 - provide effective controls to guard against theft and diversion (Internal/External)
  - Building Security
    - Physical Controls
      - Security Systems (alarm, access control, CCTV, etc.)
      - Segregated Areas (lobby, office, warehouse, parking)
    - Policy and Procedures
      - Employee entrance
      - Emergency exits monitored 24 hr by Alarm Company
      - Visitor log and badges
      - No packages (purses, backpacks, etc.) in warehouse
      - No picking aprons outside warehouse
      - Package Search Policy



# 21 CFR 1301 - Security

- 1301.72 - Physical Security Controls
  - Vault & Cage
    - Physical
      - construction (concrete, modular, wire gauge)
      - security systems (different detection sensors)
  - Policy and Procedures
    - Access lists
    - Shipping and Receiving policies (DBL check, log)
    - Inventory control
    - Accountability is key

# **21 CFR 1301 - Security**

- 1301.74 - Other Security Controls
  - Good faith inquiry
    - MOST IMPORTANT FUNCTION
    - Wholesale distributors have an express duty to verify licensure and registration status of its customers
  - Customer File Set Up
    - on-site customer inspection
    - retain copy of each customer's current registration prior to shipment of any CS or Listed Chemical products
    - DEA information entered into computer system exactly as represented on actual registration certificate
    - only delivery to address in system as printed on order form and/or registration

# 21 CFR 1301 - Security

- Customer File Maintenance
  - Customer DEA Review Report (NTIS)
    - reviewed monthly by each distribution center
    - also reviewed by CSRA
  - Federal Register review daily
  - 30 and 60 day expiration reports printed at distribution centers
  - License expiration notifications printed on invoices
  - Computer system automatically "blocks" orders of CS from customers with expired registrations
  - Computer system automatically "blocks" schedules of CS from customers not authorized

# 21 CFR 1301 - Security

- 1301.74 - Other security controls
  - Suspicious order reporting system
    - Suspicious orders include orders of unusual size, deviating substantially from a normal pattern, and/or unusual frequency
    - Automated reporting system (daily fax to DEA)
    - Flexible reporting timeframes (daily, weekly, monthly)
    - Customer specific (retail, hospital, physician, etc.)

# **21 CFR 1301 - Security**

- **1301.74 - Other security controls**
  - Theft/loss reporting (DEA Form 106)
  - Common and contract carriers
    - ABC Selection & Evaluation Checklist/Inspection
  - Narcotic Treatment Center deliveries
    - Authorized signatures on file



# **21 CFR 1301 - Security**

- **1301.90 & .93 - Employee Screening**
- Prospective employees including temporary associates

- **All Associates**

- "Justifacts" - ALL felony & misdemeanor convictions
- Drug Screens – Initial and Random

- **"Compliance Critical" Personnel**

- DEA - Drug related charges, denials, revocations, etc.
- Annual "Justifacts" criminal record checks

# **21 CFR 1304 – Records & Reports**

- 1304.04 - Maintenance of records and inventories
  - 2 years (3 years maintained per PDMA guidelines)
  - Central Recordkeeping
    - not including executed DEA Form 222's or inventories
  - Records must be made available within two business days of a written request
  - Schedule II records must be stored separately
  - Schedule III-V records stored separately or in a readily retrievable manner

# **21 CFR 1304 – Records & Reports**

- 1304.11 - Inventory requirements
  - Complete and accurate record of all controlled substances on hand on the date the inventory is taken
  - ABC Policy and Procedures regarding shipping, receiving and returns and accurate dates
- Inventories
  - Daily activity counts (detect and correct errors)
  - Monthly inventory of all Controlled Substances on hand in the building (saleable & unsaleable)
  - Year End ARCOS - Schedule II & III narcotics (Dec. 31<sup>st</sup> COB)
  - Biennial - a complete inventory within two years of Initial or last Biennial inventory (ABC - Dec. 31<sup>st</sup> every even-numbered year)

# **21 CFR 1304 – Records & Reports**

- Area of confusion during audits/inspections
- 1304.22 - Records for distributors
  - Product name, description, quantity, name, addresses, DEA registration number, for all transactions (sales, receipt, credit, debit, etc.)
  - ABC Invoice & Credit Memo (See samples)
  - All of this information is available
- 1304.33 Reports to ARCOS
  - Filed monthly
  - All Schedule II and Schedule III narcotic products



## **21 CFR 1305 - Order Forms**

- 1305.03, .06, .09 & .11 - An order form (DEA Form 222) is required for each distribution of a Schedule II controlled substance
  - Alterations, incomplete forms
  - Each DEA Form 222 is double-checked and matched against work order for accuracy and completeness
- 1305.07 - Power of Attorney
  - Authorizes other associates to sign DEA Form 222's
- 1305.15 - Cancellations
  - Purchaser cancellations
  - Supplier cancellations
- Automation (CSOS) will positively impact the Industry



# **21 CFR 1309 – Listed Chemicals**

- Registration, Recordkeeping and Reporting
- 1309.21 - (Registration) Every person who distributes List I Chemicals shall obtain annually a registration specific to List I Chemicals.....
  - Exemptions
    - DEA Controlled Substance registration
    - "retail distributor"
- 1309.23 - Separate registration for separate locations
  - System automatically blocks customers without registration

# **21 CFR 1310 - Listed Chemicals**

- 1310.03 - (Recordkeeping) Required Records
  - Regulated transactions
- 1310.04 - Maintenance of Records
  - Regular business records are acceptable
  - Current plus 2 years
  - Central location record retention acceptable
  - "Readily Retrievable"

# **21 CFR 1310 – Listed Chemicals**

- 1310.05 - (Reporting) Required Reports
  - Extraordinary quantity
  - Uncommon method of payment or delivery
  - Excessive loss or disappearance
- Reporting requirements for Chemicals are different than Controlled Substances
  - Oral notification upon discovery of loss
  - Written report must be filed within 15 days of oral notification
  - No DEA Form 106

# **Future Issues Impacting Drug Wholesalers**

- **Crime**
- **Theft/Burglary**
- **Counterfeit Product**
- **Controlled Substance Ordering System  
(CSOS)**
- **Listed Chemicals Storage Requirements**
- **Rescheduling of certain products**

# Questions ?

- Pharmaceutical Distribution Industry
- AmerisourceBergen Corporation
- Registration
- Security
- Records and Reports
- Order Forms
- Listed Chemicals